(5)

SEP 13 2004

No. 04-32

In The

Supreme Court of the United States

MEDRAD, INC.,

Petitioner,

v.

LIEBEL-FLARSHEIM COMPANY and MALLINCKRODT, INC.,

Respondents.

On Petition For Writ Of Certiorari To The United States Court Of Appeals For The Federal Circuit

REPLY BRIEF

W. THOMAS MCGOUGH, JR.
Counsel of Record
FREDERICK H. COLEN
BARRY J. COYNE
REED SMITH LLP
435 Sixth Avenue
Pittsburgh, PA 15219
(412) 288-3131

GREGORY L. BRADLEY
MEDRAD, INC.
One Medrad Drive
Indianola, PA 15051
(412) 767-2400
Attorneys for Petitioner Medrad, Inc.

COCKLE LAW BRIEF PRINTING CO (800) 225-6964
OR CALL COLLECT (402) 342-2831

TABLE OF CONTENTS

		Page
I.	THE LAW ON PATENT CLAIM CONSTRUCTION IS FAR FROM WELL-SETTLED AND REFLECTS IRRECONCILABLE CONFLICTS	2
II.	THE HOLDINGS IN THIS CASE REACH BEYOND ITS FACTS AND ARE DIRECTLY AT ISSUE IN THE *PHILLIPS EN BANC* DECISION	4
III.	RESPONDENTS MISSTATE A NUMBER OF MATERIAL FACTS IN A FAILED ATTEMPT TO DISTINGUISH THIS CASE FROM *PHILLIPS*	6
IV.	CONCLUSION	8

TABLE OF AUTHORITIES

Page

CASES

Innova/Pure Water, Inc. v. Safari Water Filtration Systems, Inc., 2004 WL 1780928 (Fed. Cir. Aug. 11, 2004) 3

Liebel-Flarsheim Co. v. Medrad, Inc., 358 F.3d 898 (Fed. Cir. 2004) 2, 3, 6

Markman v. Westview Instruments, Inc., 517 U.S. 370 (1996) 2, 6, 7

Phillips v. AWH Corp., 363 F.3d 1207 (Fed. Cir. 2004) ..... *passim*

STATUTES

Sup. Ct. R. 15.5 1

Sup. Ct. R. 15.6 1

Sup. Ct. R. 29.3 1

OTHER PUBLICATIONS

Cases and Recent Developments, 13 Fed. Cir. B. J. 719 5

Jonathan R. Spivey, *The Federal Circuit's Markman Jurisprudence – Patchwork Quilt or Jigsaw Puzzle? Is There Really Panel-Dependency and Unpredictability in Federal Circuit Opinions?* 795 PLI/Pat 709 5

REPLY

Pursuant to Supreme Court Rule 15.6, Petitioner Medrad hereby submits this Reply Brief in support of Medrad's Petition for Writ of Certiorari filed on July 1, 2004, to address new points raised in the Brief in Opposition.

Respondents' Brief in Opposition includes a number of factual and legal errors that are material to the current petition.[1] Most important of these is Respondents' contention that the law on claim construction is "well-settled" and that this case simply involved application of these "well-settled" principles to its specific facts. That contention, which permeates Respondents' entire brief, is not credible. As set forth in Medrad's Petition and Supplemental Brief, and as evidenced in the Federal Court's decision to hear seven disputed claim construction questions *en banc* in *Phillips v. AWH Corp.*, Federal Circuit Appeal Nos. 03-1269, -1286 (App. 139-60), the law on claim construction is not "well-settled" at all.

Those unsettled and conflicting claim construction principles are, moreover, at the heart of the resolution of this case. This case, which is extensively cited in the

---

[1] Respondents apparently recognized the weakness and vulnerability of their Opposition, relying as they do on errors and misrepresentations. In violation of Sup. Ct. R. 29.3, Respondents filed their Brief in Opposition with this Court via overnight delivery service on September 2, but served Medrad via regular U.S. mail. This tactic ensured that Medrad would not receive Respondents' Brief until after the long Labor Day weekend on September 7, five days after the Brief in Opposition was docketed and 4 days after it was received by this Court, thereby depriving Medrad of a significant portion of the 10 day window for filing a reply brief set forth in Sup. Ct. R. 15.5. Notwithstanding, Medrad is filing this Reply Brief within the 10 day window.

Phillips' dissent and cited in other Federal Circuit opinions as well, plainly contains holdings that have far-reaching consequences well beyond its specific facts. There is no other way to explain the Federal Circuit's repeated reliance on the analysis in this case. Given the timing of the *Phillips en banc* decision and the direct relationship between the claim construction issues raised in the cases, this Court should either hold its review of Medrad's Petition until after the *Phillips en banc* decision is rendered or grant Medrad's Petition, vacate the Federal Circuit's opinion, and remand this case back to the Federal Circuit to reconsider in light of the holdings in the *Phillips en banc* decision.

I. THE LAW ON PATENT CLAIM CONSTRUCTION IS FAR FROM WELL-SETTLED AND REFLECTS IRRECONCILABLE CONFLICTS

Respondents' argument that the law of claim construction is "well-settled" ignores almost everything that has occurred in that area of the law since this Court's decision *Markman v. Westview Instruments, Inc.*, 517 U.S. 370 (1996). Specifically, the Federal Circuit's decision to hear the *Phillips* case *en banc* to "resolve issues concerning the construction of patent claims" and the Federal Circuit's identification of seven questions (App. 133-38) – all involving the issue of claim construction – is only the most recent indication that claim construction is not "well-settled." The dissent's assertion in *Phillips* that the "majority decision" in *Phillips* "effectively limits the claims to the preferred embodiment, contrary to our recent decision in *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898 (Fed. Cir. 2004), and numerous other decisions of this court," *Phillips v. AWH Corp.*, 363 F.3d 1207, 1216 (Fed. Cir.

2004) (App. 155), simply underscores that the law on claim construction is far from settled and places this case squarely in the middle of that unsettled area.

The Federal Circuit has also acknowledged that the claim construction at issue in this case involves a "fine line" and an "inherent tension" between two axioms of claim construction: that claim terms should be read in view of the specification but that it is improper to read a limitation from the specification into the claims. *See Liebel-Flarsheim*, 358 F.3d at 904-05. The Federal Circuit noted that this tension creates a problem that can present "particular difficulties" in a case such as this one where the preferred embodiment is the only embodiment, but the claim language is sufficiently broad that it might be read to encompass features not disclosed in the written description. *Id.* at 905. Even more recently, the Federal Circuit acknowledged that the "contrasting nature of the axioms" has been a "longstanding difficulty." *Innova/Pure Water, Inc. v. Safari Water Filtration Systems, Inc.*, 2004 WL 1780928, *5 (Fed. Cir. Aug. 11, 2004).

Given the Federal Circuit's decision to rehear *Phillips en banc* on seven claim construction issues, the Federal Circuit's own acknowledgment of a "longstanding difficulty" in claim construction, and the various commentators' explanations that the Federal Circuit's decisions are in conflict that Medrad cited in its Petition, Respondents' position that claim construction, and in particular the claim construction at issue here, is "well-settled" is simply untenable.

II. THE HOLDINGS IN THIS CASE REACH BEYOND ITS FACTS AND ARE DIRECTLY AT ISSUE IN THE *PHILLIPS EN BANC* DECISION

Respondents' characterization of the arguments that Medrad is presenting as "case-specific issues not appropriate for review by this Court" ignores the recognition that this case already has received and this case's relationship to the issues in *Phillips*.

Since its publication in February of 2004, the Federal Circuit's decision in this case has been cited no less than ten times by the Federal Circuit and eight times by Federal District Courts.[2] Commentators have also cited this case a significant number of times. For example, one commentator included it as part of his recent article in his

---

[2] *Phillips v. AWH Corp.*, 363 F.3d 1207 (Fed. Cir. 2004); *Home Diagnostics, Inc. v. Lifescan, Inc.*, 2004 WL 1925613 (Fed. Cir. Aug 31, 2004); *In re Bigio*, 2004 WL 1878752 (Fed. Cir. Aug 24, 2004); *Innova/Pure Water, Inc. v. Safari Water Filtration Systems, Inc.*, 2004 WL 1780928 (Fed. Cir. Aug 11, 2004); *Mars, Inc. v. H.J. Heinz Co.*, 377 F.3d 1369 (Fed. Cir. 2004); *Zimmer, Inc. v. Howmedica Osteonics Corp.*, 2004 WL 1194248 (Fed. Cir. May 26, 2004); *In re American Academy of Science Tech Center*, 367 F.3d 1359 (Fed. Cir. 2004); *Housey Pharmaceuticals, Inc. v. Astrazeneca UK Ltd.*, 366 F.3d 1348 (Fed. Cir. 2004); *Novartis Pharmaceuticals Corp. v. Eon Labs Mfg., Inc.*, 363 F.3d 1306 (Fed. Cir. 2004); *Gaus v. Conair Corp.*, 363 F.3d 1284 (Fed. Cir. 2004); *Rambus, Inc. v. Infineon Technologies AG*, 2004 WL 1822386 (E.D. Va. Aug 12, 2004); *Honeywell Intern, Inc. v. ITT Industries, Inc.*, 2004 WL 1774773 (E.D. Mich. Aug 5, 2004); *Lifetime Products, Inc. v. GSC Technology Corp.*, 321 F.Supp.2d 938 (N.D. Ill. 2004); *Dow Agrosciences LLC v. Crompton Corp.*, 2004 WL 1087362 (S.D. Ind. May 12, 2004); *AGFA Corp. v. Creo Products, Inc.*, 2004 WL 1882623 (D. Mass. Aug 24, 2004); *Agere Systems, Inc. v. Broadcom Corp.*, 2004 WL 1658530 (E.D. Pa. Jul 20, 2004); *Lifetime Products, Inc. v. Correll, Inc.*, 323 F.Supp.2d 1129 (D. Utah Jun 30, 2004); and *Ardisam, Inc. v. Ameristep, Inc.*, 2004 WL 1725166 (W.D. Wis. Aug 2, 2004).

"Federal Circuit Claim Construction Canon Outline." Jonathan R. Spivey, *The Federal Circuit's Markman Jurisprudence – Patchwork Quilt or Jigsaw Puzzle? Is There Really Panel-Dependency and Unpredictability in Federal Circuit Opinions?* 795 PLI/Pat 709, 723. Yet another commentator indicated that the Federal Circuit's decision in this case sent a "strong message" on an issue of claim construction. *Cases and Recent Developments*, 13 Fed. Cir. B. J. 719, 762.

The citation of this case a significant number of times in such a short time period confirms that this is an important case in the area of claim construction and not simply a run of the mill application of "well-settled" law to specific facts.

Moreover, given that the dissent in *Phillips* cited this case eight times, *see Phillips* 363 F.3d at 1216-19 (App. 154-60), and the identity of the issues involved in these two cases as set forth in Medrad's Supplemental Brief, there is little question that the Federal Circuit's decision in this case will play a role in the Federal Circuit's *en banc* decision in *Phillips*. Maintaining close contact between this case and *Phillips* will ensure that this case remains consistent with the jurisprudence of claim construction that will result from the *en banc* decision in *Phillips*.

In sum, given the significant number of citations to this case in such a short period and the commonality of issues between this case and the issues to be considered *en banc* by the Federal Circuit in *Phillips*, Respondents' argument that the Petition for Certiorari should simply be denied is without merit.

III. RESPONDENTS MISSTATE A NUMBER OF MATERIAL FACTS IN A FAILED ATTEMPT TO DISTINGUISH THIS CASE FROM *PHILLIPS*

It is clear on the record that the Federal Circuit relied on an extrinsic dictionary definition to expand the coverage of Respondents' patent claims to cover an invention that Respondents' inventors did not invent. That outcome places this case squarely within the issues to be addressed by the Federal Circuit *en banc* in *Phillips* and squarely in conflict with this Court's precedent in *Markman*. Respondents misstate a number of material facts to try to avoid this conclusion.

First and foremost, Respondents incorrectly suggest that this case was not "decided based on extrinsic dictionary definitions." *See* Opposition Brief at 12. The record is clear, however, that the Federal Circuit's construction of the term "opening" as simply an "aperture" in "common usage," *Liebel-Flarsheim*, 358 F.3d at 905, was based upon the extrinsic dictionary definition of "opening" cited by the District Court. (App. 51) (*citing* Webster's Third New International Dictionary).

Second, Respondents wrongly argue that Medrad was "unable" to "point to a clear disavowal of claim scope in either the written description or the prosecution histories." *See* Opposition Brief at 12. Medrad specifically submitted written citations to the record clearly pointing out where the disavowal of claim scope could be located in the written descriptions and prosecution histories of the patents in issue. (App. 165-66).

Third, Respondents incorrectly argue that it is "uncontested" that "L-F was the first to invent a front-loading

powered medical injector and that the claims asserted in this action are directed to that broad invention." *See* Opposition Brief at 18. Medrad has always argued that L-F's invention, and the claims of its patents, are limited to a front-loading powered medical injector *with a pressure jacket*. (App. 49). In fact, the district court specifically noted that it was Medrad who, at a trade show in November 1992, "introduced the first pressure jacketless, front-loading CT injector system for disposable syringes." (App. 39).

Fourth, Respondents incorrectly assert that "the record below fully supported the fact that the inventors had conceived of both design alternatives, i.e., with and without a pressure jacket." *See* Opposition Brief at 18. The record below is clear that the inventors for the Respondents never got an injector without a pressure jacket to work and abandoned the idea. As one of Respondents' inventors admitted in an internal memorandum well after Respondents filed their patent: "We investigated in the beginning the possibility of not using a pressure sleeve [i.e., jacket]. Our testing indicated that this option was too risky. . . ." (App. 167).

Given a correct rendition of the facts, this case clearly involves the same issues the Federal Circuit will address *en banc* in *Phillips*; namely, whether it is appropriate to look first and foremost to intrinsic evidence or extrinsic dictionary definitions in defining claim terms. Given this alignment with the issues in *Phillips* and the conflict between the Federal Circuit's decision in this case and this Court's precedent in *Markman*, the issues raised in Medrad's petition are appropriate for consideration and review by this Court or at least for preservation pending the *en banc* decision in *Phillips*.

IV. CONCLUSION

The current state of the law on claim construction is not "well-settled" as Respondents suggest. As evidenced by the Federal Circuit's decision to address seven fundamental questions on claim construction *en banc* in *Phillips v. AWH Corp.*, the law on claim construction is in conflict. Given the far-reaching holding in this case and the direct connection between the issues in this case and *Phillips*, this Court should either hold Medrad's Petition for review until after the *Phillips en banc* decision is rendered or grant Medrad's Petition, vacate the Federal Circuit's opinion and remand this case to the Federal Circuit as Medrad requested.

DATED: September 10, 2004

Respectfully submitted,

W. THOMAS MCGOUGH, JR.
Counsel of Record
FREDERICK H. COLEN
BARRY J. COYNE
REED SMITH LLP
435 Sixth Avenue
Pittsburgh, PA 15219
(412) 288-3131

GREGORY L. BRADLEY
MEDRAD, INC.
One Medrad Drive
Indianola, PA 15051
(412) 767-2400

Attorneys for Petitioner Medrad, Inc.

HOWREY SIMON ARNOLD & WHITE

HOWREY ATTORNEYS AT LAW

[Names and Addresses Omitted in Printing]

(Filed Nov. 7, 2003)

November 6, 2003

Via Hand Delivery

Mr. Jan Horbaly
Clerk of Court
United States Court of Appeal
for the Federal Circuit
717 Madison Place, N.W.
Washington, DC 20439

RE: Liebel-Flarsheim Company et al. v. Medrad, Inc., Appeal Nos. 03-1082, -1165

Dear Mr. Horbaly:

During oral argument in the above-captioned appeal on Tuesday morning, November 4, 2003, Judge Dyk asked where in the '669 and '261 patents appellee Medrad finds support for the District Court's construction of the claims terms "syringe receiving opening" and "opening." At that time, I did not have the particular pin-point citations to the intrinsic evidence of record available to me at the podium. The following are those pin-point citations:

In the '669 patent:

Column 2, line 64 to Column 3, line 1 (A0183-A0184).
Abstract, lines 1-10 (A0171).

In the '261 patent:

> Column 2, lines 61-65 (A0205).
> Abstract, lines 1-10 (A0193).

In the prosecution history of L-F's Original Patent Application, to which the '669 and '261 patents claim priority:

> Page 39 and the original 89 claims (A3025-A3072) viewed in conjunction with:
>
> amended claims 109 (A3109-A3110) and 114 (A3111-A3112) that were added in the prosecution of the original application by an Amendment (A3103-A3116); and
>
> the "Remarks" and claims in a Supplemental Amendment (A3121-A3137) filed during prosecution of the original application and in particular, the statement that "The claims proposed at the interview, which are claims 119-125, are more concise than those they replace and clarify the inventive concepts claimed." (A3131)

In the prosecution history of the '261 Patent:

> The statement in the "remarks" portion of a Preliminary Amendment (A2510-A2526) that: "This divisional application is filed to more particularly claim embodiments of the invention not previously specifically claimed, particularly as illustrated in Figs. 15-17 of the drawings of the application, and particularly described on page 37, line 21 to page 39, line 3 of the specification of the application." (A2525)

We hereby respectfully request that these pin-point citations be provided to Judges Lourie, Dyk and Bryson who sat on the panel that heard the oral argument in the

above-captioned appeal. Thank you in advance for your attention to this matter.

HOWREY SIMON ARNOLD &
WHITE LLP

By: /s/ James F. Davis
James F. Davis

cc J. Robert Chambers, Esq.
(via facsimile)

Liebel-Flarsheim **LF**
Interoffice Memo

TO Dane Battiato DATE December 4, 1992
FROM Frank Fago SUBJECT Medrad Front Load Injector

As we have seen, Medrad has shown a front load injection system at the RSNA. Attached is a sketch that illustrates their configuration. The attributes of Medrad front load system include;

- 200 ml
- Adapts to there existing injector
- Requires no pressure sleeve
- Mounted at the rear flange
- Built in catheter retention system
- Clear
- Gamma Sterilizable
- Split cavity mold

Syringe Material

An engineer from Medrad told me that their syringe material was PET (Polyethyiene terephthalate). PET is a good candidate for a syringe since it is clear, has good chemical resistance, is gamma resistant, and has good mechanical properties. The original material we selected for the syringe barrel was Ektar, which is in the PET family. We ended up not using Ektar for the syringe because our molder couldn't reliably run the material. Unfortunately, there is no turning back since the shrink rates are dramatically different. (*Polypropylene = .020 in/in; PET = .004 in/in*)

Cost

I believe that Medrad's syringe costs is about the same as ours. Their increased cost incurred due to additional and more expensive material along with an increased mold cycle time is offset by our additional costs for the Umbrella Cap and Nut. (*PET costs about 12.8 ¢/in^3 verses 1.4 ¢/in^3 for Polypropylene.*)

Structural Integrity

We investigated in the beginning the possibility of not using a pressure sleeve. Our testing indicated that this option was too risky at 300 psi due to syringe ballooning and the possibility of blow by. Medrad's maximum pressure is probably no greater than 200 psi. Even at pressures of 200 psi there is still a problem with ballooning which increases the time that contrast continues to flow after the injection is stopped.

User Interface

Our CT9000 user interface and console is far superior to Medrad's including a shorter cycle time. Our plunger is located at the top of the syringe which reduces the cycle time. They have wasted time to expel air before filling the syringe and the time to retract the ram after the injection so another syringe can be loaded. They will not be able to move the plunger to the top of the syringe with there present system because

* * *